

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS

PATTIE POKORNY AND
CHRISTOPHER POKORNY (H/W),

Plaintiffs,

vs.

ELI LILLY AND COMPANY, an Indiana
corporation,

Defendant.

No. 4:14-CV-2960

**ANSWER TO PLAINTIFFS’
COMPLAINT
DEMAND FOR JURY TRIAL**

Defendant Eli Lilly and Company (“Lilly”), by and through its undersigned attorney,
hereby files its Answer and Defenses to Plaintiffs’ Complaint.

INTRODUCTION

1. Lilly admits that it manufactures, markets, and sells Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions and other labeled risks and benefits of the medications. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 1 and therefore denies the same.

PARTIES

2. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 2 and therefore denies the same.

3. Lilly admits that it is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Lilly also admits that it is engaged in the business of research, development, testing, manufacturing, producing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Lilly denies the remaining allegations in Paragraph 3.

JURISDICTION AND VENUE

4. Lilly admits that this Court has subject matter jurisdiction in the form of diversity jurisdiction.

5. Lilly admits that it is authorized to conduct business and does conduct business in Texas. Lilly denies the remaining allegations on the basis that they purport to allege conclusions of law and thus do not require a response.

6. Lilly denies the allegations in Paragraph 6.

7. Paragraph 7 purports to allege conclusions of law and thus does not require a response and on that basis Lilly denies the allegations.

FACTUAL ALLEGATIONS

8. Paragraph 8 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

9. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed and sold Prozac®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly admits that Prozac® is in the class of prescription medications known as selective serotonin reuptake inhibitors (“SSRIs”), but denies the relevance of the information. Lilly admits that the United States Food and Drug Administration (“FDA”) approved Prozac® in 1987 as a safe and effective medication for the treatment of Major Depressive Disorder (“MDD”). Lilly admits that Prozac®’s patent expired in August 2001. Allegations pertaining to SSRIs as a class of antidepressants are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 9.

10. Lilly admits that Cymbalta® is a serotonin norepinephrine reuptake inhibitor (“SNRI”). Allegations pertaining to statements made about SNRIs are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 10.

11. Lilly denies the allegations in Paragraph 11.

12. Lilly admits that the FDA approved Cymbalta® in 2004 for the treatment of Major Depressive Disorder (“MDD”). Lilly further admits that the FDA approved Cymbalta® for the treatment of Generalized Anxiety Disorder (“GAD”) in 2007 and fibromyalgia in 2008. Lilly denies the remaining factual allegations in Paragraph 12.

13. Lilly admits that the FDA approved Cymbalta® in 2004. Lilly also admits that it researched, tested, developed, manufactured, labeled, marketed, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly further admits that it promoted Cymbalta® to prescribers through its sales representatives. The allegations pertaining to the promotion of Cymbalta® utilizing Lilly sales representatives are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 13.

14. Lilly denies the allegations in Paragraph 14.

15. Lilly admits that the half-life of a drug is the time it takes for the concentration of the drug in the body to be reduced by one-half. Lilly further admits that, since 2004, the Cymbalta® label has stated that the half-life of Cymbalta® is approximately 12 hours. Lilly denies the remaining factual allegations in Paragraph 15.

16. Lilly admits that Paragraph 16 contains an accurate partial quotation from the 2004 Cymbalta® label. Lilly denies the remaining allegations in Paragraph 16 as characterized by Plaintiffs.

17. Lilly admits that the risk of discontinuation symptoms from antidepressant therapy was a well understood clinical phenomenon for decades prior to Cymbalta®’s approval and that the need for tapering off of antidepressant therapy was also well understood. Lilly denies the remaining factual allegations in Paragraph 17.

18. Lilly denies the allegations in Paragraph 18. Answering further, Lilly notes that the cited article speaks for itself.

19. Lilly denies the allegations in Paragraph 19. Answering further, Lilly notes that the Cymbalta® label speaks for itself.

20. Lilly admits that the Cymbalta® label has included a warning on discontinuation symptoms since Cymbalta® was approved by the FDA in 2004. Lilly admits that the Cymbalta® label contains the following “WARNINGS AND PRECAUTIONS” section regarding “Discontinuation of Treatment with Cymbalta®”:

Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue. During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta®. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate

Paragraph 20 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the remaining allegations.

21. Lilly denies the allegations in Paragraph 21. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiffs refer in Paragraph 21 of the Complaint when read in context and its entirety. Lilly denies the remaining allegations in Paragraph 21.

22. Paragraph 22 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 22.

23. Lilly admits that the package insert for Cymbalta® warns of potential discontinuation symptoms, such as “dizziness, nausea, headache, paresthesia, vomiting, irritability, and nightmare.” Lilly denies the remaining factual allegations in Paragraph 23.

24. Lilly admits that Cymbalta® is designed as delayed-release capsules at dosages of 20 mg, 30 mg, and 60 mg. Lilly further admits that Cymbalta® should be swallowed whole. Lilly denies the remaining allegations in Paragraph 24.

25. Lilly denies the allegations in Paragraph 25.

26. The allegations pertaining to the sales and profitability of Cymbalta® are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 26 as characterized by Plaintiffs.

27. Lilly denies the allegations in Paragraph 27.

28. Lilly denies the allegations in Paragraph 28.

29. Lilly denies the allegations in Paragraph 29.

30. Paragraph 30 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiff’s alleged injuries and therefore denies the same.

31. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 31 and therefore denies the same.

32. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 32 and therefore denies the same.

33. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 33 and therefore denies the same.

34. Lilly denies the allegations in Paragraph 34.

35. Lilly denies the allegations in Paragraph 35.

36. Paragraph 36 (a) - (f) purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiffs' alleged injuries and therefore denies the same.

FIRST CAUSE OF ACTION

NEGLIGENCE

37. Lilly reincorporates and realleges its Responses to Paragraphs 1-36 of Plaintiffs' Complaint as if fully set forth herein.

38. Paragraph 38 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risks associated with the use of Cymbalta®.

39. Paragraph 39 (a) - (l) purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 39 (a) - (l).

40. Paragraph 40 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 40.

41. Lilly denies the allegations in Paragraph 41. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 41 relating to Plaintiff's alleged injuries and therefore denies the same.

42. Paragraph 42 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 42 relating to Plaintiff's alleged injuries and therefore denies the same.

43. Lilly denies the allegations in Paragraph 43, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 43. Lilly denies that Plaintiffs are entitled to any such relief.

SECOND CAUSE OF ACTION

STRICT PRODUCT LIABILITY – DESIGN DEFECT

44. Lilly reincorporates and realleges its Responses to Paragraphs 1-43 of Plaintiffs' Complaint as if fully set forth herein.

45. Lilly admits that it is engaged in the business of research, development, testing, manufacturing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 45 and therefore denies the same.

46. Insofar as Plaintiffs intended to allege that Lilly manufactured, marketed, promoted, and sold a product that was merchantable and/or reasonably suited to the use intended, Lilly admits the allegation. Insofar as Plaintiffs intended to allege that Lilly manufactured, promoted, and sold a product that was *not* merchantable, Lilly denies the allegation. Lilly further admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 46 and therefore denies the same.

47. Lilly denies the allegations in Paragraph 47.

48. Lilly denies the allegations in Paragraph 48.

49. Lilly denies the allegations in Paragraph 49.

50. Paragraph 50 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, the allegations in Paragraph 50 are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

51. Paragraph 51 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 51 relating to Plaintiff's alleged injuries and therefore denies the same.

52. Lilly denies the allegations in Paragraph 52, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 52. Lilly denies that Plaintiffs are entitled to any such relief.

THIRD CAUSE OF ACTION

STRICT PRODUCT LIABILITY – FAILURE TO WARN

53. Lilly reincorporates and realleges its Responses to Paragraphs 1-52 of Plaintiffs' Complaint as if fully set forth herein.

54. Lilly admits that it researched, tested, developed, manufactured, labeled, distributed, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly further admits that it has utilized direct-to-consumer advertising for Cymbalta®, in conformity with applicable rules and regulations. Lilly objects to the term "persons responsible for consumers" as vague and ambiguous and on that basis denies the allegation. Paragraph 54 further purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 54.

55. Paragraph 55 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

56. Plaintiffs' allegation pertaining to "exclusive control" is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegation. Lilly denies the remaining allegations in Paragraph 56.

57. Lilly denies the allegations in Paragraph 57.

58. Paragraph 58 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 58.

59. Paragraph 59 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 59.

60. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 60 relating to Plaintiff's alleged use of Cymbalta® and therefore denies the same.

61. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiff or Plaintiff's physician's ability to discover any alleged "defect in the drug" and therefore denies the same. Lilly denies any remaining allegations in Paragraph 61.

62. Lilly admits that it is engaged in the business of researching, developing, testing, manufacturing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Paragraph 62 purports to allege conclusions of law that do not require a response and on that basis, Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 62.

63. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 63 relating to Plaintiff's knowledge and therefore denies the same. Lilly denies the remaining allegations in Paragraph 63.

64. Paragraph 64 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 64.

65. Lilly denies the allegations in Paragraph 65.

66. Lilly denies the allegations in Paragraph 66.

67. Paragraph 67 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 67 relating to Plaintiff's alleged injuries and therefore denies the same.

68. Lilly denies the allegations in Paragraph 68, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 68. Lilly denies that Plaintiffs are entitled to any such relief.

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

69. Lilly reincorporates and realleges its Responses to Paragraphs 1-68 of Plaintiffs' Complaint as if fully set forth herein.

70. Paragraph 70 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risks associated with the use of Cymbalta®.

71. Lilly denies the allegations in Paragraph 71.

72. Paragraph 72 purports to allege a conclusion of law that does not require a response and on that basis Lilly denies the allegations. Lilly further denies the remaining allegations in Paragraph 72.

73. Lilly denies the allegations in Paragraph 73.

74. Lilly denies the allegations in Paragraph 74. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 74 and therefore denies the same.

75. Paragraph 75 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 75 relating to Plaintiff's alleged injuries and therefore denies the same.

76. Paragraph 76 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 76 relating to Plaintiff's alleged injuries and therefore denies the same.

77. Lilly denies the allegations in Paragraph 77, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 77. Lilly denies that Plaintiffs are entitled to any such relief.

FIFTH CAUSE OF ACTION

FRAUD

78. Lilly reincorporates and realleges its Responses to Paragraphs 1-77 of Plaintiffs' Complaint as if fully set forth herein.

79. Paragraph 79 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Answering further, Lilly notes that the text of *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), speaks for itself.

80. Lilly denies the allegations in Paragraph 80.

81. Lilly denies the allegations in Paragraph 81.

82. Lilly denies the allegations in Paragraph 82 (a) - (i).

83. Lilly denies the allegations in Paragraph 83.

84. Paragraph 84 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 84 and therefore denies the same.

85. Paragraph 85 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 85 and therefore denies the same.

86. Lilly denies the allegations in Paragraph 86.

87. Paragraph 87 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

88. Lilly denies the allegations in Paragraph 88.

89. Paragraph 89 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies the remaining allegations in Paragraph 89.

90. Paragraph 90 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 90, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 90. Lilly denies that Plaintiffs are entitled to any such relief.

91. Paragraph 91 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 91 relating to Plaintiff's alleged injuries and therefore denies the same.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

92. Lilly reincorporates and realleges its Responses to Paragraphs 1-91 of Plaintiffs' Complaint as if fully set forth herein.

93. Lilly denies the allegations in Paragraph 93.

94. Paragraph 94 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 94 relating to Plaintiff's alleged injuries or Plaintiff's alleged "discontinuation" of Cymbalta® and therefore denies the same.

95. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 95 and therefore denies the same.

96. Paragraph 96 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

97. Paragraph 97 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 97 relating to Plaintiff's injuries and therefore denies the same.

98. Paragraph 98 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 113 relating to Plaintiff's alleged injuries and therefore denies the same.

99. Lilly denies the allegations in Paragraph 99, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 99. Lilly denies that Plaintiffs are entitled to any such relief.

SEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

100. Lilly reincorporates and realleges its Responses to Paragraphs 1-99 of Plaintiffs' Complaint as if fully set forth herein.

101. Lilly lacks the knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 101 and therefore denies the same.

102. Paragraph 102 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 102 relating to Plaintiffs' alleged injuries and therefore denies the same.

103. Lilly denies the allegations in Paragraph 103, except that Lilly admits only that Plaintiffs seek the relief set forth in Paragraph 103. Lilly denies that Plaintiffs are entitled to any such relief.

104. Lilly denies each and every allegation in Plaintiffs' Complaint not specifically admitted herein.

PRAYER FOR RELIEF

Lilly denies the allegations in this section of Plaintiffs' Complaint, except that Lilly admits only that Plaintiffs seek the relief set forth in this section. Lilly denies that Plaintiffs are entitled to any relief whatsoever.

DEMAND FOR JURY TRIAL

This section of Plaintiffs' Complaint does not assert any allegation requiring a response. To the extent a response is deemed necessary, Lilly admits that Plaintiffs request a trial by jury.

GENERAL DENIAL AND DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Lilly in this matter. Lilly, therefore, asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Lilly may withdraw any of these defenses as may be appropriate. Further, Lilly reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Lilly states the following:

FIRST DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening or superseding cause or causes.

FIFTH DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Lilly to warn Plaintiff directly of alleged dangers associated with the use of Cymbalta®, such claims are barred under the learned intermediary doctrine because Lilly has discharged its duty to warn in its warnings to the prescribing physician.

SIXTH DEFENSE

To the extent that Plaintiffs asserts claims based on Lilly's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SEVENTH DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

EIGHTH DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by application of the doctrine of comparative fault. Lilly invokes the provisions of Section 33.001 and Section 33.013 of the Texas Civil Practice and Remedies Code in the unlikely event that liability is established by Plaintiffs in this case.

NINTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Lilly or other manufacturer.

TENTH DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Lilly and over whom Lilly had not control and for whom Lilly may not be held accountable.

ELEVENTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Cymbalta®.

TWELFTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural course of conditions for which this Defendant is not responsible.

THIRTEENTH DEFENSE

To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs did not rely on any act, omission, or representation made by Lilly.

FIFTEENTH DEFENSE

To the extent that Plaintiffs seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Lilly's state and federal rights.

SIXTEENTH DEFENSE

No act or omission of Lilly was willful, wanton, malicious, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

SEVENTEENTH DEFENSE

Plaintiffs have not suffered any actual injury or damages.

EIGHTEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

NINETEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part because Lilly provided legally adequate "directions or warnings" as to the use of Cymbalta® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement of (Second) of Torts.

TWENTIETH DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-FIRST DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Cymbalta®. Plaintiffs' causes of action are barred in whole or in part by their failure to assert a safer design for Cymbalta.

TWENTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FOURTH DEFENSE

Plaintiffs' claims are barred in whole or in part because Lilly's conduct conforms with medical knowledge.

TWENTY-FIFTH DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SIXTH DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Lilly denies, then it was unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-SEVENTH DEFENSE

Lilly's advertisement and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Texas Constitutions.

TWENTY-EIGHTH DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

TWENTY-NINTH DEFENSE

Lilly made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or any representations of any nature whatsoever to the Plaintiffs.

THIRTIETH DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Lilly in any state in the United States was manufactured and

distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-FIRST DEFENSE

With respect to each and every purported cause of action, the acts of Lilly were at all times done in good faith and without malice.

THIRTY-SECOND DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Lilly knew or should have known and which gave rise to a duty to warn, Lilly at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-THIRD DEFENSE

Plaintiffs' claims against Lilly are barred because Plaintiff's treating physicians fully informed Plaintiff of the risks associated with the use of Cymbalta. Any informed consent and/or release given by Plaintiff is pleaded as an affirmative defense.

THIRTY-FOURTH DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000).

THIRTY-FIFTH DEFENSE

Plaintiffs' claims for pre-judgment and post-judgment interest are limited by the dates and amounts set forth in the following:

- (a) Art. 5069-1.05 § 6, TEX. R. CIV. STAT.;
- (b) Chapter 304, TEXAS FINANCE CODE; and
- (c) Chapter 41, TEX. CIV. PRAC. & REM. CODE.

THIRTY-SIXTH DEFENSE

Any recovery by Plaintiffs for medical or healthcare expenses should be limited to the amount actually paid or incurred. TEX. CIV. PRAC. & REM. CODE § 41.0105. Specifically, Plaintiffs are not entitled to an award of damages for medical bills for which no obligation to pay exists and/or ever existed.

THIRTY-SEVENTH DEFENSE

Plaintiffs' damages claims are barred by the economic loss doctrine.

THIRTY-EIGHTH DEFENSE

Plaintiffs' claims of fraud are barred by reason of the Complaint's failure to allege the factual circumstances constituting the alleged fraud with particularity.

THIRTY-NINTH DEFENSE

Lilly fully asserts § 82.001 and § 82.007 of the Texas Civil Practice and Remedies Code and states that Cymbalta® complied with mandatory safety standards or regulations adopted and promulgated by the federal government that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

FORTIETH DEFENSE

Plaintiffs' claims may be barred by failure to join indispensable parties.

FORTY-FIRST DEFENSE

Any claims relating to alleged communications with regulatory agencies of the U.S. government are barred in whole or in part by operation of Lilly's First Amendment right to petition the government (the *Noerr-Pennington* Doctrine).

FORTY-SECOND DEFENSE

To the extent Plaintiffs assert a demand for punitive damages, Lilly specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon*

Shipping Co. v. Baker, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

FORTY-THIRD DEFENSE

Any claim for punitive damages is limited by § 41.003 of the Texas Civil Practice and Remedies Code which requires proof by “clear and convincing evidence.”

FORTY-FOURTH DEFENSE

To the extent that Plaintiffs assert a claim for punitive damages, that claim is in contravention of the rights of Lilly under the following constitutional provisions:

- a. Plaintiffs’ claim for punitive damages violates, and is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the Texas Constitution, on grounds including the following:
 - i. the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Texas Constitution;
 - ii. the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Texas Constitution;
 - iii. the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Texas Constitution;

- iv. the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the Texas Constitution;
- v. the award of punitive damages to Plaintiffs in this action would constitute a deprivation of property without due process of law; and
- vi. the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTY-FIFTH DEFENSE

Any claim for punitive damages is limited by § 41.008 of the Texas Civil Practice and Remedies Code to two times the amount of economic damages, plus an amount equal to non-economic damages, not to exceed \$750,000.00, or \$200,000.00, whichever is greater. Lilly asserts all other defenses and limitations on punitive damages contained in Chapter 41 of the Texas Civil Practice and Remedies Code.

FORTY-SIXTH DEFENSE

The determination of the amount of punitive damages, if any, should be bifurcated from the remaining issues pursuant to § 41.009 of the Texas Civil Practice and Remedies Code and *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994).

FORTY-SEVENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Cymbalta® was designed, manufactured, distributed, marketed, and labeled with proper warnings, information, cautions, and instructions, in accordance with the state of the art and the state of scientific and technological knowledge. Lilly invokes all state of the art defenses applicable to Plaintiffs' claims, including the state of the art applicable to the industry in question, medicine, medical science, and all others, alleging that it discharged, according to law and due care, each and every duty which Plaintiffs may have been owed.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Lilly to determine all of its legal, contractual, and equitable rights, Lilly reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Lilly will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Lilly respectfully demands judgment dismissing the Complaint with prejudice and awarding Lilly its reasonable costs and disbursements, including reasonable attorneys' fees, together with such and other and further relief that the court may deem just and proper.

JURY DEMAND

Lilly demands a trial by jury as to all issues triable.

DATED this 14th day of November, 2014.

By: /s/ Stephen Scheve

Stephen E. Scheve (attorney-in-charge)

Texas Bar No. 00794928

S.D. Tex. Bar No. 18784

Reed Smith LLP

811 Main Street, Suite 1700

Houston, TX 77002-6110

sscheve@reedsmith.com

Telephone: +1 713 469 3800

Facsimile: +1 713 469 3899

Attorney for Defendant

ELI LILLY AND COMPANY

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this instrument has been served upon all counsel of record via email and/or ECF on November 14, 2014.

David Friend, Esq.
HISSEY KIENTZ, LLP
One Arboretum Plaza
9442 Capital of Texas Hwy N., Suite 400
Austin, TX 78759
Tel: (512) 320-9100 / Fax: (512) 320-9101

Michael D. Woerner, Esq.,
mwoerner@kellerrohrback.com
Meredith Gray, Esq.,
mgray@kellerrohrback.com
Alison S. Gaffney, Esq.,
agaffney@kellerrohrback.com
KELLER ROHRBACK L.L.P.
1201 Third Avenue, Suite 3200
Seattle, WA 98101
Tel.: (206) 623-1900 / Fax: (206) 623-3384

Khesraw Karmand (CA Bar No. 280272)
kkarmand@kellerrohrback.com
KELLER ROHRBACK L.L.P.
1129 State Street, Suite 8
Santa Barbara, CA 93101
Tel: (805) 456-1496 / Fax: (805) 456-1497

Michael L. Baum (SBN: 119511)
mbaum@baumhedlundlaw.com
Bijan Esfandiari (SBN: 223216)
besfandiari@baumhedlundlaw.com
R. Brent Wisner (SBN: 276023)
rbwisner@baumhedlundlaw.com
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Tel: (310) 207-3233 / Fax: (310) 820-7444

Harris L. Pogust, Esq.
hpogust@pbmattorneys.com
T. Matthew Leckman, Esq.
MLEckman@pbmattorneys.com
POGUST BRASLOW MILLROOD LLC
161 Washington Street, Suite 1520
Conshohocken, PA 19428
Tel.: (800) 897-8930 / Fax: (610) 941-4245

/s/ Stephen E. Scheve
Stephen E. Scheve